UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,738	10/12/2004	Mitsuaki Kawamura	04676.0142	8582

22852 7590 10/04/2007

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
KAROL, JODY LYNN	
ART UNIT	PAPER NUMBER
4133	

MAIL DATE	DELIVERY MODE
10/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,738	KAWAMURA ET AL.	
	Examiner	Art Unit	
	Jody L. Karol	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *10-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/12/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/13/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/JP03/04247 International Filing Date: 4/3/2003, which claims priority to JP 2002-106300. Claims 1-38 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) filed on 1/13/2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on Application No. 2002-106300 filed in the Japan on 4/9/2002.

Election/Restrictions

3. Applicant's election without traverse of Group I, claims 1-9, drawn to a composition for cell proliferation containing a purine nucleic acid-related substance and a pyrimidine nucleic acid-related substance, in the reply filed on 9/6/2007 is acknowledged.

Upon further consideration by the examiner, the species election requirement dated 8/7/2007 is withdrawn.

Claims 10-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-9 are examined on the merits herein.

Specification

4. The abstract of the disclosure is objected to because the term "comprising" in line 14 is not in the proper tense. Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: the terms "(W/V%)" and "ratio of cont." on page 11 of the specification are unclear. The units for "(W/V%)" are not indicated and the "ratio of cont." is not defined. The specification also has extraneous spacing between words (see for example pages 14 and 19). Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.

(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: Nucleic Acid Based Composition for Cell Proliferation.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-15 of copending Application No. 10/574696.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a composition for cell proliferation containing a purine nucleic acid-related substance and a pyrimidine nucleic acid-related substance while the copending claims are drawn to the same composition for promoting collagen production. The recitation of "for cell proliferation" in the instant claims and "for promoting collagen production" in the copending claims have not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gil et al. (US 4,544,559).

The instant claims are drawn to compositions for cell proliferation containing a purine nucleic acid-related substance and pyrimidine nucleic acid-related substance. The terms containing is considered to be broad and open-ended. Claim 2 further limits the purine nucleic acid-related substance to being selected from adenine nucleic acid substances and the pyrimidine nucleic acid-related substance from being selected from uracil nucleic acid-related substances. Claim 3 limits the purine nucleic acid-related substance to adenosine monophosphate or salt thereof, and the pyrimidine nucleic acid-related substance to uridine monophosphate or salt thereof.

Gil et al. teaches a composition for nucleotide enriched humanized milk containing the nucleotides cytidine monophosphate (CMP), guanosine monophosphate (GMP) and inosine monophosphate (IMP), adenosine monophosphate (AMP), and uridine monophosphate (UMP) (see abstract and column 1, lines 64-68). Therefore, all the limitations of claims 1-3 are met.

Claim 6 further limits the composition of claim 1 to containing the pyrimidine nucleic acid related substance in a ratio of 0.01 to 100 parts by weight per part by weight of the purine nucleic acid-related substance.

Gil et al. further teaches that the concentration of the nucleotides in a powdered form of the milk are: 1.12 mg/100 g of CMP (0.00112% by weight); 1.32 mg/100 g of AMP (0.00132% by weight); 1.49 mg/100mg GMP (0.00149% by weight); 3.42 mg/100 g of UMP (0.00342% by weight); and 0.45 mg/100 g IMP (0.00045% by weight) (see abstract, column 11, Table V, and claim 1). AMP, GMP, and IMP are purine nucleic acid-related substances while CMP and UMP are pyrimidine nucleic acid-related substances. The ratio of pyrimidine to purine nucleic acid-related substances is 0.00454% by weight to 0.00731% by weight or approximately 0.621 parts by weight per pyrimidine nucleic acid-related substance per part by weight of purine nucleic acid-related substance. Therefore, the limitations of the instant claim 6 are met.

Claims 7-9 indicate intended uses for the composition of claim 1, including anti-wrinkle, anti-aging, anti-dandruff, wound healing, and hair growth effects, etc. Note that the intended use of a product carries no patentable weight. Therefore, the limitations of the instant claims 7-9 are also met.

9. Claims 1-2 and 4-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gazzani (US 5,053,230).

Claims 1-2 and 6-9 are discussed above. Claim 4 further limits the composition of claim 1 to containing the purine nucleic acid-related substance in at least 0.01% by

weight. Claim 5 further limits the composition of claim 1 to containing the purine nucleic acid-related substance in 0.01 to 10% by weight. Gazzani teaches a cosmetic preparation comprising a nutrient medium that is active as revitalizing agent for the skin, an anti-wrinkle agent, and as a factor for enhancing hair growth (see abstract). Gazzani further discloses that nutrient medium contains the purine nucleic acid-related substances adenine sulfate (1.2799% by weight), 5-AMP (adenosine-5'-monophosphate) (0.0256% by weight), and ATP disodium salt (1.2799% by weight), and the pyrimidine nucleic acid-related substances thiamine HCl (0.0384% by weight), thymine (0.0384% by weight), and uracil (0.0384% by weight) (see column 4, lines 1-28), and gives examples of formulations including the nutrient medium for anti-wrinkle products, etc. for the skin (see columns 4-5, examples 1-3). Therefore, all the claim limitations of claims 1-2 and 7-9 are met.

The purine nucleic acid-related substances are present in the nutrient in medium in a total of 2.5854% by weight, meeting the limitations of the instant claims 4 and 5. The pyrimidine nucleic acid-related substances are present in the nutrient medium in 0.0780% by weight. Therefore, the pyrimidine nucleic acid substances are in 0.0302 parts by weight per part by weight of the purine nucleic acid substance, meeting the limitations of the instant claim 6.

10. Claims 1-2 and 4-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gazzani (US 5,182,269).

Claims 1-2 and 4-9 are discussed above.

Gazzani teaches a composition for topical use containing depolymerized deoxyribonucleic acid containing purine and pyrimidine bases having hair stimulating, anti-dandruff, and anti-seborrhoic activity (see title and abstract). The purine nucleic acid substances are present in the depolymerized deoxyribonucleic acid as follows: adenine in 8.0-10.0% by weight, and guanine in 7.0-9.5% by weight. The pyrimidine nucleic acid substances are present in the depolymerized deoxyribonucleic acid as follows: cytosine in 5.5-7.5% by weight, and guanine in 8.0-11.0% by weight (see column 6, lines 23-31). Therefore, the limitations of the instant claims 1-2 and 7-9 are met. In addition, the ratio of pyrimidine to purine nucleic acid-related substances is approximately 1:1, meeting the limitations of the instant claim 6.

Gazzani further disclose that the depolymerized deoxyribonucleic acids are present in the hair lotions between 1 to 5% (see column 9, lines 10-15 and column 10, examples 9-10). This results in the purine nucleic acid-related substances being present in the composition in weight percentages from 0.15% to 0.975% by weight, meeting the limitations of the instant claims 4-5.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Masor et al. (US 5,602,109) is important for its disclosure of a nutritional formula comprising CMP, UMP, GMP, and AMP.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571) 274-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JLK

JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER